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RE: FluMist Vaccine

Dr. Jody Sachs
Vaccines and Related Biologic Products Advisory Committee
FDA
Fax: 301-827-0294

Dear Dr. Sachs:

It is my understanding that FluMist (live, cold adapted, attenuated, intranasal influenza vaccine) has not been directly tested on children who have previously received standard intramuscular influenza vaccine. This group not only comprises many healthy children, especially those currently 6-24 months of age, but more importantly all of our high-risk patients for whom influenza immunization is most important. It does not appear to be difficult to include previously immunized children in trials, rather than limit the trials to "virgin" children.

I hope that the FDA Advisory Committee will consider requiring direct testing of previously immunized children, rather than depend on indirect or proxy models, in the licensing of this product. Pediatricians must be sure that the new vaccine is safe and efficacious in our high-risk and healthy patients who have previously received standard influenza immunization.

Thank you.



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